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| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | RAO, MANJUNATH N | |
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| | | | 1652 | |

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,725

Applicant(s)

PROUTY ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-13 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-13 and 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g. 6) ☐ Other:

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DETAILED ACTION

Claims 3-13, 21-31 are currently pending and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-13 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that Examiner has not shown that there would be a serious burden if restriction were not required. This is not found persuasive because while the searches for the two groups may overlap, they are not coextensive. The search for Groups I and II would each require the search of subclasses unnecessary for the search of elected Group I. Furthermore, the search is not limited to patent databases but involves extensive non-patent literature databases as well.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-13, 21-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the polynucleotide comprising nucleotides 1 to about position 3958 or 3910 of SEQ ID NO:15 as a promoter sequence activating the transcription of a polynucleotide encoding a polypeptide, does not reasonably provide enablement for either making a variant of said polynucleotide comprising modification of 1-50 bases or for using said polynucleotide or its variant for any other use. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 3-13, 21-31 are so broad as to encompass making variants of nucleotides 1-3910 or 1-3958 of SEQ ID NO:15 and using such polynucleotides for any or all processes. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the making of the variant polynucleotides and method of use of said polynucleotide or its variants for any purpose. It would require undue experimentation of the skilled artisan to make and use the claimed polynucleotides with an undefined function/activity. Since polynucleotides

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with a promoter activity have specific highly conserved and consensus sequences at specific positions, those skilled in the art would require the guidance and knowledge as to which specific nucleotide positions can be modified without affecting the promoter activity of the polynucleotide. Similarly, since polynucleotides can have a varied functional characteristics starting from encoding a polynucleotide to regulating or stabilizing transcription those skilled in the art would require guidance and knowledge as to which specific methods or processes are encompassed for use of the polynucleotide. Without such information those skilled in the art would not know how to make and how to use said polynucleotides. The specification is limited to teaching the use of polynucleotide (nucleotides 1 to 3910 or 3958 of SEQ ID NO:15) as a promoter but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polynucleotides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polynucleotide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art

would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of nucleotides 1 to 3910 or 3958 of SEQ ID NO:15 because the specification does not establish: (A) regions of the polynucleotide structure which may be modified without affecting promoter activity; (B) the general tolerance of said promoter to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any of the 1-50 nucleotide positions with an expectation of obtaining the desired biological function; (D) a rational and predictable scheme to use the claimed polynucleotide and its variants to specific purposes or processes; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making the variant polynucleotides and determination of use of said polynucleotides is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Claims 21- 25, 30, 3-7, 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules that not been described n the specification.

The specification does not contain any disclosure of the function of all DNA sequences that are encompassed n the claims. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins or having various functions. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 21-25, 30, 3-7, 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Birren et al. (Database GenEmbl. Accession No. AC018783, 3-14-2000). This rejection is based upon the

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public availability of a polynucleotide sequence information in a public database. Claims 21-25, 30, 3-7, 12 of the instant application are drawn to an isolated polynucleotide comprising a nucleotide sequence from about nucleotide position 1 to about nucleotide position 3910 or 3958 or a variant thereof wherein said variant comprises deletions, additions, insertions and/or substitutions of from 1 to 50 bases of said sequences, vector and host cell comprising said polynucleotides. Birren et al. disclose a polynucleotide comprising a polynucleotide that is 99.3% identical to SEQ ID NO :15 comprising 2 deletions and 3 modified nucleotides. The reference also discloses vectors and host cells (clones) comprising said polynucleotide. Therefore, Birren et al. anticipate claims 21-25, 30, 3-7, 12 as written.


Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.


MANJUNATH N. RAO
PATENT EXAMINER

Manjunath N. Rao
October 3, 2003